UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

May 1, 2024
Date of Report (date of earliest event reported)

Corcept Therapeutics Incorporated

(Exact name of registrant as specified in its charter)

Delaware	**000-50679**	**77-0487658**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

149 Commonwealth Drive, Menlo Park, CA 94025
(Address of Principal Executive Offices) (Zip Code)

(650) 327-3270
Registrant's telephone number, including area code

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	CORT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

☐

Item 2.02. Results of Operations and Financial Condition.

Item 7.01 Regulation FD Disclosure.

On May 1, 2024, Corcept Therapeutics Incorporated (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2024 and a corporate update. The press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 2.02 and Item 7.01 and the information contained in the press release attached as Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information in this Item 2.02 and Item 7.01 and the information contained in the press release attached as Exhibit 99.1 is not incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in the filing unless specifically stated so therein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibits No.	Description
99.1	Press Release of Corcept Therapeutics Incorporated, dated May 1, 2024
104.1	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CORCEPT THERAPEUTICS INCORPORATED

Date: May 1, 2024

By: /s/ Atabak Mokari
Name: Atabak Mokari
Title: Chief Financial Officer

EXHIBIT 99.1

CORCEPT THERAPEUTICS ANNOUNCES FIRST QUARTER FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

MENLO PARK, Calif., (May 1, 2024) – Corcept Therapeutics Incorporated (NASDAQ: CORT), a commercial-stage company engaged in the discovery and development of medications to treat severe endocrinologic, oncologic, metabolic and neurologic disorders by modulating the effects of the hormone cortisol, today reported its results for the quarter ended March 31, 2024.

Financial Results

- *Revenue of $146.8 million, a 39 percent increase over the same period in 2023*
- *Increase in 2024 revenue guidance to $620 – $650 million, from $600 – $630 million*
- *Net income per common share of $0.25 (diluted), compared to $0.14 in first quarter 2023*
- *Cash and investments of $451.0 million as of March 31, 2024*

"There were a record number of new Korlym® prescribers in the first quarter and a record number of patients receiving Korlym. Physicians are increasingly aware that hypercortisolism is much more prevalent than was previously assumed, so they are screening more patients for the disorder," said Joseph K. Belanoff, MD, Corcept's Chief Executive Officer. "When Korlym is prescribed, we use the expertise and infrastructure that we have developed and refined over many years to support physicians and patients. This additional care helps create a life-changing impact for patients who receive Korlym treatment."

Corcept's first quarter 2024 revenue was $146.8 million, compared to $105.7 million in the first quarter of 2023. First quarter operating expenses were $117.3 million, compared to $90.8 million in the first quarter of 2023, due to increased clinical trial activity and expenses to support the expansion of our commercial team. Net income was $27.8 million in the first quarter of 2024 compared to $15.9 million in the same period last year. Cash and investments were $451.0 million at March 31, 2024 compared to $425.4 million at December 31, 2023.

The company increased its 2024 revenue guidance to $620 – $650 million.

Clinical Development

"The results of the open-label phase of our GRACE trial, which we released last week, are compelling," said Dr. Belanoff. "We expect to build on these results in the trial's randomized withdrawal phase. Results from this portion of the study will be available in the coming weeks. We are on track to submit our NDA for relacorilant in Cushing's syndrome by the end of this quarter.

"In addition, we have completed enrollment in all our other late-stage studies – GRADIENT, CATALYST, ROSELLA and DAZALS. We expect that these studies will provide potent evidence that cortisol modulation is a powerful therapeutic mechanism with activity in many serious disorders," added Dr. Belanoff. "We expect data from these trials by the end of this year."

Cushing's Syndrome

- *GRACE – Phase 3 trial of relacorilant in patients with all etiologies of hypercortisolism – open-label phase demonstrated clinically meaningful and statistically significant improvements in hypertension, hyperglycemia, weight, waist circumference, cognitive impairment and quality of life; results from randomized withdrawal phase expected this quarter*
- *Relacorilant New Drug Application (NDA) – NDA submission for Cushing's syndrome expected this quarter*

- *GRADIENT – Phase 3 trial of relacorilant in patients with Cushing's syndrome caused by adrenal adenomas – enrollment completed; results expected in the fourth quarter*
- *CATALYST – Phase 4 trial examining the prevalence of hypercortisolism in patients with difficult-to-control type 2 diabetes; patients with hypercortisolism may enter a randomized, double-blind, placebo-controlled study of Korlym – enrollment completed; preliminary results: approximately 25% of patients enrolled were found to have hypercortisolism; full prevalence phase results expected this quarter and treatment phase results expected by year-end*

"Relacorilant has demonstrated tremendous promise as a treatment for patients with Cushing's syndrome. Patients in GRACE's open-label phase exhibited significant improvements across a broad range of clinically meaningful endpoints, without significant safety burden. All patients have now completed the randomized withdrawal phase of the study. We plan to present data from both the open-label and randomized withdrawal phases of the study at a medical conference in June," said Bill Guyer, PharmD, Corcept's Chief Development Officer.

"Our CATALYST trial is the largest and most rigorous study ever conducted to establish the prevalence of hypercortisolism in patients with difficult-to-control diabetes. We believe that CATALYST will be a landmark study to guide physicians as they identify and treat patients with hypercortisolism. We will present final results from the prevalence phase at the American Diabetes Association's 84th Scientific Sessions in June," said Dr. Guyer.

Oncology

- *ROSELLA – Pivotal Phase 3 trial of relacorilant plus nab-paclitaxel in patients with platinum-resistant ovarian cancer – enrollment completed; results expected by year-end*
- *Open-label, Phase 1b trial of relacorilant plus pembrolizumab in patients with adrenal cancer with cortisol excess – enrollment completed; results expected by mid-year*
- *Randomized, placebo-controlled, Phase 2 trial of relacorilant plus enzalutamide in patients with prostate cancer in collaboration with the University of Chicago – enrollment continues*

"Fully enrolling ROSELLA takes us a big step closer to addressing the unmet medical need of women with platinum-resistant ovarian cancer. Relacorilant has the potential to become the standard of care for patients with this devastating disease. We expect progression-free survival data, ROSELLA's primary endpoint, by the end of this year," said Dr. Guyer.

Amyotrophic Lateral Sclerosis (ALS)

- *DAZALS – Randomized, double-blind, placebo-controlled, Phase 2 trial of dazucorilant in patients with ALS – enrollment completed; results expected by year-end*

"Better treatments for ALS are urgently needed. Dazucorilant showed great promise in an animal model of ALS – improving motor performance and reducing neuroinflammation and muscular atrophy. Fully enrolling DAZALS is an important step toward understanding dazucorilant's potential for significantly improving outcomes for people living with this devastating disease. We expect data by the end of this year," said Dr. Guyer.

Non-alcoholic Steatohepatitis (NASH)

- *MONARCH – Randomized, double-blind, placebo-controlled, Phase 2b trial of miricorilant in patients with biopsy-confirmed NASH – enrollment continues*

"In our Phase 1b study, miricorilant reduced liver fat very rapidly, improved liver health and key metabolic and lipid measures, and was well-tolerated. We look forward to building on these promising results in our MONARCH study," said Dr. Guyer. "This drug has the potential to greatly benefit the millions of patients with NASH."

Conference Call

We will hold a conference call on May 1, 2024, at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). Participants must register in advance of the conference call by clicking here. Upon registering, each participant will receive a dial-in number and a unique access PIN. Each access PIN will accommodate one caller. Additionally, a listen-only webcast will be available by clicking here. A replay of the call will be available on the Investors / Events tab of Corcept.com.

About Corcept Therapeutics

For over 25 years, Corcept's focus on cortisol modulation and its potential to treat patients across a wide variety of serious disorders has led to the discovery of more than 1,000 proprietary selective cortisol modulators. Corcept's advanced clinical trials are being conducted in patients with hypercortisolism, solid tumors, ALS and NASH. In February 2012, the company introduced Korlym®, the first medication approved by the U.S. Food and Drug Administration for the treatment of patients with Cushing's syndrome. Corcept is headquartered in Menlo Park, California. For more information, visit Corcept.com.

Forward-Looking Statements

Statements in this press release, other than statements of historical fact, are forward-looking statements based on our current plans and expectations that are subject to risks and uncertainties that might cause our actual results to differ materially from those such statements express or imply. These risks and uncertainties include, but are not limited to, our ability to operate our business and generate sufficient revenue to fund our activities; the availability of competing treatments for hypercortisolism, including the potential for rapid uptake or discounted pricing of generic versions of Korlym; our ability to obtain acceptable prices and adequate insurance coverage and reimbursement for Korlym; risks related to the development of relacorilant, dazucorilant, miricorilant and our other product candidates, including their clinical attributes, regulatory approvals, mandates, oversight and other requirements; the timing, cost and outcome of legal disputes and investigations; and the scope and protective power of our intellectual property. These and other risks are set forth in our SEC filings, which are available at our website and the SEC's website.

In this press release, forward-looking statements include those concerning: favorable trends in medical practice, our continued revenue growth and 2024 revenue guidance, which may be adversely affected by changing technology, government pricing regulations and increased uptake or price reductions in competing medications, including generic versions of Korlym; the rates of screening and treatment for hypercortisolism; cortisol modulation's potential to treat serious diseases; development of relacorilant as a treatment for Cushing's syndrome and ovarian, adrenal and prostate cancer; the design, timing and expectations regarding our GRACE and GRADIENT trials; the timing and disposition of relacorilant's NDA in Cushing's syndrome; the design, timing and expectations regarding our CATALYST trial; the design, timing and expectations of our ROSELLA trial and the potential for relacorilant plus nab-paclitaxel to become a standard of care; the design, timing and expectations of our DAZALS trial of dazucorilant in patients with ALS; the design, timing and expectations of our MONARCH trial in patients with NASH; and the accrual and attributes of clinical data, as well as the timing of regulatory submissions with respect to, all of our development activities. We disclaim any intention or duty to update forward-looking statements made in this press release.

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	March 31, 2024	December 31, 2023[1]
	(Unaudited)	
Assets		
Cash and investments	$ 451,037	$ 425,397
Trade receivables, net of allowances	61,518	41,123
Insurance recovery receivable related to Melucci litigation	—	14,000
Inventory	15,036	15,974
Operating lease right-of-use asset	61	120
Deferred tax assets, net	97,870	90,605
Other assets	30,413	34,298
Total assets	$ 655,935	$ 621,517
Liabilities and Stockholders' Equity		
Accounts payable	$ 12,557	$ 17,396
Accrued settlement related to Melucci litigation	—	14,000
Operating lease liabilities	76	151
Other liabilities	95,438	83,265
Stockholders' equity	547,864	506,705
Total liabilities and stockholders' equity	$ 655,935	$ 621,517

[1] *Derived from audited financial statements at that date*

CORCEPT THERAPEUTICS INCORPORATED

CONDENSED CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share data)

	Three Months Ended March 31,	
	2024	**2023**
Revenues		
Product revenue, net	$ 146,808	$ 105,654
Operating expenses		
Cost of sales	2,535	1,386
Research and development	58,505	40,851
Selling, general and administrative	56,268	48,564
Total operating expenses	117,308	90,801
Income from operations	29,500	14,853
Interest and other income	5,493	3,581
Income before income taxes	34,993	18,434
Income tax expense	(7,231)	(2,555)
Net income	$ 27,762	$ 15,879
Net income attributable to common stockholders	$ 27,514	$ 15,807
Basic net income per common share	$ 0.27	$ 0.15
Diluted net income per common share	$ 0.25	$ 0.14
Weighted-average shares outstanding used in computing net income per common share		
Basic	102,791	107,885
Diluted	109,915	115,425

CONTACT:
Corcept Therapeutics
Investor Relations
ir@corcept.com
www.corcept.com